

public interest while giving appropriate recognition to the legitimate interests of others who have contributed to the invention.

[20 FR 6749, Sept. 14, 1955]

§8.1 Conditions to be included in research grants.

Subject to legislative directives or Executive orders providing otherwise, all grants in aid of research shall provide as a condition that any invention arising out of the activities assisted by the grant shall be promptly and fully reported, and shall provide either:

(a) That the ownership and manner of disposition of all rights in and to such invention shall be subject to determination by the Assistant Secretary (Health and Scientific Affairs) or

(b) That the ownership and disposition of all domestic rights shall be left for determination by the grantee institution in accordance with the grantee's established policies and procedures, with such modifications as may be agreed upon and specified in the grant, provided the Assistant Secretary (Health and Scientific Affairs) finds that these are such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties, and provided the Government shall receive a royalty-free license, with a right to issue sublicenses as provided in §8.3, under any patent applied for or obtained upon the invention.

(c) Wherever practicable, any arrangement with the grantee pursuant to paragraph (b) of this section shall provide in accordance with Executive Order 9865 that there be reserved to the Government an option, for a period to be prescribed, to file foreign patent applications upon the invention.

[20 FR 6749, Sept. 14, 1955, as amended at 31 FR 12842, Oct. 1, 1966]

§8.2 Determination as to domestic rights.

Rights in any invention not subject to disposition by the grantee pursuant to §8.1(b) are for determination by the Assistant Secretary (Health and Scientific Affairs) as follows:

(a) If he finds that there is adequate assurance that the invention will ei-

ther be effectively dedicated to the public, or that any patent which may be obtained thereunder will be generally available for royalty-free and nonexclusive licensing, the effectuation of these results may be left to the grantee.

(b) If he finds that the invention will thereby be more adequately and quickly developed for widest use and that there are satisfactory safeguards against unreasonable royalties and repressive practices, the invention may be assigned to a competent organization for development and administration for the term of the patent or such lesser period as may be deemed necessary.

(c) If he finds that the interest of another contributing Government agency is paramount to the interest of the Department of Health and Human Services, or when otherwise legally required or in the public interest, the invention may be left for disposition by that agency in accordance with its own policy.

(d) In all other cases, he shall require that all domestic rights in the invention shall be assigned to the United States unless he determines that the invention is of such doubtful importance or the Government's equity in the invention is so minor that protective measures, except as provided in §8.3, are not necessary in the public interest.

[20 FR 6749, Sept. 14, 1955, as amended at 31 FR 12842, Oct. 1, 1966]

§8.3 Licenses to the Government.

Any arrangement or determination as to the disposition of rights in inventions pursuant to §§8.1, 8.2, 8.5 or 8.6 shall require that there be reserved under any patent application or patent thereon, domestic or foreign, a non-exclusive, irrevocable, royalty-free license to the Government with power to sublicense for all governmental purposes.

[22 FR 9696, Dec. 4, 1957]

§8.4 Option to acquire foreign rights.

In any case where it is determined that all domestic rights should be assigned to the Government, there shall

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be reserved to the Government, pursuant to Executive Order 9865 (3 CFR, 1943-1948 Comp.) and Government-wide regulations issued thereunder, an option to require the assignment of all rights in the invention in all or in any specified foreign countries. In any case where the inventor is not required to assign the patent rights in any foreign country or countries to the Government, or the Government fails to exercise its option within such period of time as may be provided by regulations issued by the Chairman of the Government Patents Board any application for a patent which may be filed in such country or countries by the inventor or his assignee shall nevertheless be subject to a nonexclusive, irrevocable, royalty-free license to the Government for all governmental purposes, including the power to sublicense for all governmental purposes.

[20 FR 6750, Sept. 14, 1955]

§ 8.5 Fellowships.

In the discretion of the Assistant Secretary (Health and Scientific Affairs), the award of a fellowship to a person not a Government employee may provide for the reporting of any invention made during the term thereof, and for its disposition in accordance with the provisions of § 8.1(a) or for its disposition by the institution at which the research was performed in accordance with its established policies, if applicable to such an invention, which meet the requirements of paragraph (b) of such section.

[22 FR 9695, Dec. 4, 1957, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.6 Contracts for research.

(a) Contracts for research, with other than nonprofit institutions, shall provide that any invention first conceived or actually reduced to practice in the course of the performance of the contract shall be promptly and fully reported to the Assistant Secretary (Health and Scientific Affairs) for determination by him as to the manner of disposition of all rights in and to such invention, including the right to require assignment of all rights to the United States or dedication to the public. In the exercise of this power the or-

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ganization head will be guided by the policy specified in § 8.2 with respect to grants.

(b) Contracts for research with nonprofit institutions shall contain provisions as in paragraph (a) of this section except that, if it is determined that the institution's policies and procedures are acceptable as meeting the requirements of § 8.1(b) with respect to grants, the contract may provide, with such special stipulations in the contract as may be deemed necessary in the public interest, for leaving the ownership and disposition of all domestic rights for determination by the contracting institution in accordance with such policies and procedures.

[23 FR 1215, Feb. 27, 1958, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.7 Cancer chemotherapy industrial research contracts.

Notwithstanding the provisions of § 8.6, the Surgeon General in the negotiation of contracts with other than nonprofit organizations for the cancer chemotherapy research program shall be subject only to such limitations and alternatives as the Assistant Secretary (Health and Scientific Affairs) may approve for such program.

[22 FR 9696, Dec. 4, 1957, as amended at 31 FR 12842, Oct. 1, 1966]

§ 8.8 Screening of compounds generated under DHHS grants and awards.

(a) *General policy.* (1) Chemical compounds having potential medicinal and other utilities are often synthesized or identified during the course of research financed under DHHS research grants and awards. Reporting, filing patent applications on, and determining ownership in inventions relating to such compounds pose problems which require special attention. After a compound has been synthesized, it generally will not constitute a patentable invention under the patent laws of the United States until a specific utility for the compound has been established. It is the policy of the Department that all compounds synthesized or identified during the course of grant-supported research should be adequately screened